

### **REMARKS**

Claims 1, 2, 7, 10, 20 and 21 are now pending.

#### **I. Obviousness**

The Action alleges that the claims are unpatentable over WO 98/29375 (“Atlas”) in view of US 6,303,139 (“Passi”) and in further view of Delack et al. (US 2003/0113309 A1). Applicant respectfully traverses the rejection.

The Action alleges that Atlas teaches using compound J to treat oxidative stress; that Passi teaches oxidative stress is involved in MS; and that Delack further teaches that MS patients have an anti-oxidant deficiency.

#### **A. Many diseases are associated with oxidative stress**

Applicant does not dispute that oxidative stress is involved in MS. For that matter, oxidative stress is also involved in **many other** diseases processes, both of a neurological and non-neurological origin – for example: acute respiratory distress syndrome, amyotrophic lateral sclerosis, atherosclerotic cardiovascular disease, multiple organ dysfunction, Parkinson's disease, Alzheimer's disease, basal ganglia degenerative diseases, motoneuron diseases, Scrapie, spongiform encephalopathy and Creutzfeldt-Jakob's disease.

Surely the Action is not suggesting that treating **all** of these diseases would be obvious to the skilled artisan. Similarly, the mere teaching that oxidative stress is associated with MS does not make it obvious that a given compound will actually be successful in treating MS.

B. Many compounds are known anti-oxidants – but **possibly one** has been shown to treat MS

As Applicant has asserted in previous responses, there are many known anti-oxidant compounds – the subject inventor estimates there to be at least 50 to 100 known compounds. However, by data such as the animal model disclosed in the subject application, at most **only one other** has been shown to treat MS. The table attached hereto again shows all current approved drugs for MS and all compounds that are in phase II or III for MS. As can be seen, **none** of the approved drugs are thought to treat MS due to antioxidant activities. And of the tested drugs, **only one** in phase II (inosine) is an anti-oxidant. And even this compound has a dual action - as an anti-oxidant and a promoter for rewiring of neurons.

Thus, given that no data existed – except for the possibility of one other compound – showing that an anti-oxidant can treat MS, the skilled artisan would not have inferred from Atlas, Passi and Delack that it would have been obvious to actually treat MS with compound J.

As an example of compounds unable to treat MS, Applicant previously provided an article teaching that vitamins C and E did not reduce the risk of MS. In response, the Action states that this article does not show that vitamins C and E cannot treat MS.

Applicant respectfully disagrees. In the group studied, 214 cases of MS were documented. Thus, by showing from this population that the risk of MS was not reduced – because so many cases of MS actually developed while taking these vitamins - the article is also showing that vitamins C and E do not effectively treat the disease either.

Of course, the skilled artisan would also assume that no other anti-oxidant, including vitamins C and E, can treat MS. If such an anti-oxidant could treat MS, the data would be published. And if it could not treat MS, the data would likely not be published – failures rarely get published, the data regarding vitamins C and E being a rare exception.

Moreover, the Action goes on to say that "just because not many antioxidants are known to treat multiple sclerosis is by no means an indicator that one cannot be used to treat multiple sclerosis." This is what is known as an "irrelevant truth." It is not relevant whether a given compound "can possibly" be used to treat MS.

Rather, the relevant truth is as follows: Because, at best, only one anti-oxidant compound – out of the 50 to 100 known anti-oxidant compounds - is known to treat multiple sclerosis, it is an indicator that if one is discovered to treat multiple sclerosis, it is an unobvious discovery.

In summary, associating MS with oxidative stress is not enough to render compound J obvious for treating MS. Firstly, many diseases have been associated with oxidative stress. The skilled artisan would hardly consider it obvious to actually treat any or all of these diseases with a given anti-oxidant compound. Secondly, of the 50 to 100 known anti-oxidant compounds, possibly only one other was known to treat MS. Indeed, compounds such as vitamins C and E have been shown to not be effective. Thus, the mere showing that a given compound is an anti-oxidant is not sufficient to make it obvious for actually treating MS.

For all these reasons, Applicant respectfully requests that this rejection be withdrawn.

In re Application of: Daphne ATLAS et al  
Serial No.: 10/522,766  
Filed: February 27, 2006  
Office Action Mailing Date: August 28, 2009

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Examiner: FINN Meghan R.  
Group Art Unit: 1614  
Attorney Docket: 29287

### **CONCLUSION**

In view of the above amendments and remarks it is respectfully submitted that the claims are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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#### **Enclosures:**

- Petition for Extension (Three Months)
- Additional Claims Transmittal Fee
- Current therapies for MS (table)